# **Complete Summary**

## **GUIDELINE TITLE**

Evidence based clinical practice guideline for the management of systemic hypertension following orthotopic cardiac transplantation.

## BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for the management of systemic hypertension following orthotopic cardiac transplantation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2002 Apr 5. 9 p. [28 references]

## **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
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CATEGORIES

#### **SCOPE**

## DISEASE/CONDITION(S)

IDENTIFYING INFORMATION AND AVAILABILITY

Systemic hypertension following orthotopic cardiac transplantation

# **GUIDELINE CATEGORY**

Evaluation Management Treatment

# CLINICAL SPECIALTY

Cardiology Critical Care Family Practice Pediatrics Surgery

#### INTENDED USERS

Advanced Practice Nurses Nurses Physician Assistants Physicians

# GUIDELINE OBJECTIVE(S)

To provide a clinical guideline for the effective medical management of systemic hypertension following orthotopic cardiac transplantation

## TARGET POPULATION

These guidelines are intended primarily for use in infants and children undergoing orthotopic cardiac transplantation, aged 0 to 17 years of age.

These guidelines do <u>not</u> address all considerations needed to manage those with the following:

- Presence of significant left ventricular dysfunction
- Hepatic insufficiency

#### INTERVENTIONS AND PRACTICES CONSIDERED

### Evaluation

Clinical assessment through the monitoring of systemic arterial blood pressure

# Treatment

- 1. Nicardipine infusion
- 2. Amlodipine
- 3. Beta-blockers (note cautions)
- 4. Angiotensin-converting enzyme (ACE) inhibitors (note cautions)

## MAJOR OUTCOMES CONSIDERED

- Medication side effects
- Risk of cardiovascular complications

## METHODOLOGY

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic and critical literature reviews, using a grading scale, and examined current local clinical practices.

During formulation of these guidelines, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

**COST ANALYSIS** 

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines have been reviewed and approved by clinical experts not involved in the development process, senior management, Risk Management & Corporate Compliance, the Institutional Review Board, other appropriate hospital committees, and other individuals as appropriate to their intended purposes.

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

Each recommendation is followed by evidence grades (A-X) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

#### Clinical Assessments

- 1. It is recommended that systemic arterial blood pressure be maintained within the normal range for age following orthotopic cardiac transplantation (see Table 1 in the original guideline document).
  - Note 1: Continuous monitoring of arterial blood pressure via an arterial line is recommended during the early postoperative period.
  - Note 2: Blood pressure may be affected by pain. Normal values assume adequate pain control.

#### Treatment Recommendations

- Nicardipine infusion is recommended in the acute postoperative period for treatment of systemic hypertension. Initiating dose is 0.5 micrograms/kg/min infusion titrated to a maximum dose of 5 micrograms/kg/min (Flynn et al., 2001 [D]).
  - Note: Other traditional intravenous agents have potential side effects: cyanide toxicity with nitroprusside, increase of myocardial oxygen consumption with hydralazine and diazoxide, and heart block and heart failure with beta-blockers.
- 2. It is recommended that amlodipine be initiated at 0.1 mg/kg/day to achieve an arterial blood pressure below the 90th percentile for age. Dosing frequency may be adjusted from once daily (Qday) to twice daily (BID) if indicated. Maximum dose is 0.6 mg/kg/day up to 20 mg/day (Flynn et al., 2000 [B]; Khattak et al., 1998 [D]; Pfammatter et al., 1998 [B]; Tallian et al., 1999 [B]).

Note 1: Drug levels may be affected when used in conjunction with cytochrome P450 system inducers or inhibitors. Amlodipine can affect cyclosporine A (CSA) levels early on (Pesavento et al., 1996 [B]).

Note 2: Amlodipine has a 6-hour onset of clinical effect and a 35 to 48 hour elimination half-life. It has a 60 to 65% bioavailability, with food having little effect on absorption. It undergoes extensive hepatic metabolism, and for this reason can be used in renal insufficency, but should be avoided in hepatic failure. Its duration of action is related to the drug itself, rather than its formulation, and thus it can be crushed or placed in suspension. Side effects reported in children include palpitations, constipation, edema, and heartaches (Pfammatter et al., 1998 [B]). Several investigators report that children and infants seem to require higher doses on a per kilogram basis. Another common finding is that children often require twice-daily dosing to maintain effective blood pressure (BP) control (Flynn et al., 2000 [B]). In addition, due to its long half-life, dose adjustments should be made 5 to 7 days apart.

- 3. If systemic hypertension persists on maximal therapy with calcium channel blockers, the following concomitant drug therapy should be considered:
  - a. Beta-blockers
    - Note: Beware of relative contraindications of asthma, diabetes, bradycardia, and hypercholesterolemia.
  - b. Angiotensin-converting enzyme (ACE) inhibitors Note: Beware of use in renal insufficiency.

## **Definitions**:

Evidence Based Grading Scale:

- A: Randomized controlled trial: large sample
- B: Randomized controlled trial: small sample
- C: Prospective trial or large case series
- D: Retrospective analysis
- E: Expert opinion or consensus
- F: Basic laboratory research
- S: Review article
- M: Meta-analysis
- Q: Decision analysis
- L: Legal requirement
- O: Other evidence
- X: No evidence

CLINICAL ALGORITHM(S)

None provided

# EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and classified for each recommendation (see "Major Recommendations") using the following scheme:

# Evidence Based Grading Scale:

- A: Randomized controlled trial: large sample
- B: Randomized controlled trial: small sample
- C: Prospective trial or large case series
- D: Retrospective analysis
- E: Expert opinion or consensus
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- S: Review article
- M: Meta-analysis
- Q: Decision analysis
- L: Legal requirement
- O: Other evidence
- X: No evidence

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Appropriate medical management of systemic hypertension following orthotopic cardiac transplantation as demonstrated by reduced cardiovascular complications in these patients

#### POTENTI AL HARMS

- o Amlodipine: Side effects in children include palpitations, constipation, edema, and heartaches.
- o Beta-blockers: Potential for heart block and heart failure
- Angiotensin-converting enzyme (ACE) inhibitors: Potential for worsening hyperkalemia and azotemia and precipitating acute renal failure in the setting of renal artery stenosis.

## CONTRAINDICATIONS

# **CONTRAINDICATIONS**

Beta-blockers

Relative contraindications of asthma, diabetes, bradycardia, and hypercholesterolemia

Angiotensin-Converting Enzyme (ACE) Inhibitors

Beware of use in renal insufficiency

## QUALIFYING STATEMENTS

## QUALIFYING STATEMENTS

These recommendations result from review of literature and practices current at the time of their formulations. This protocol does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the guidelines to meet the specific and unique requirements of individual patients. Adherence to this pathway is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

## IMPLEMENTATION OF THE GUIDELINE

#### DESCRIPTION OF IMPLEMENTATION STRATEGY

Appropriate companion documents have been developed to assist in the effective dissemination and implementation of the guideline.

The implementation process for each Cincinnati Children's Hospital Medical Center (CCHMC) guideline is a phase in a larger process of Guideline Development. This process is utilized for every guideline but is not addressed in the content of every guideline.

At the start of each guideline, a projected implementation date is determined. Reservations for education are then made (Grand Rounds, Patient Services Inservices). When the guideline is complete and enters into the Approval Process, education planning begins. Changes created by the guideline are outlined as well as anticipated outcomes. The implementation date is confirmed. Education is provided. The guideline is implemented and pilot information collection started. The Guideline Coordinator makes daily rounds and eligible children are followed to document the use of the guideline. The implementation phase aids in finding areas for improvement or question. When issues identified are improved, the guideline progresses to the monitoring phase.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

# BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for the management of systemic hypertension following orthotopic cardiac transplantation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2002 Apr 5. 9 p. [28 references]

**ADAPTATION** 

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Apr 5

GUIDELINE DEVELOPER(S)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

**GUIDELINE COMMITTEE** 

Clinical Effectiveness Team for Management of Post Transplant Lymphoproliferative Disease (PTLD)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

**GUIDELINE STATUS** 

This is the current release of the guideline.

**GUIDELINE AVAILABILITY** 

Electronic copies: Available in Portable Document Format (PDF) from the Cincinnati Children's Hospital Medical Center Web site.

For information regarding the full-text guideline, print copies, or evidence based practice support services contact the Children's Hospital Medical Center Health Policy and Clinical Effectiveness Department at <a href="https://example.com/HPCEInfo@chmcc.org">HPCEInfo@chmcc.org</a>.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

**NGC STATUS** 

This NGC summary was completed by ECRI on March 11, 2004.

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